IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., MERZ PHARMA GMBH & CO. KGAA, and MERZ PHARMACEUTICALS GMBH,	)	
Plaintiffs,	)	C.A. No. 08-21-GMS
v.	)	**PUBLIC VERSION**
COBALT LABORATORIES INC., LUPIN PHARMACEUTICALS, INC., LUPIN LTD., ORCHID PHARMACEUTICALS INC., ORCHID CHEMICALS & PHARMACEUTICALS LTD. (d/b/a ORCHID HEALTHCARE), TEVA PHARMACEUTICALS USA, INC., UPSHER-SMITH LABORATORIES, INC., WOCKHARDT USA INC., and WOCKHARDT LIMITED,	)	
Defendants.	)	

AFFIDAVIT OF SATISH SRINIVASAN

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Attorneys for Defendants
Orchid Pharmaceuticals Inc., and
Orchid Chemicals & Pharmaceuticals Ltd.

Dated: March 3, 2008
Public Version Dated: March 7, 2008
853489 / 32657

I, Satish Srinivasan, declare and state as follows:

1. I sit on the board of directors for Orchid Pharmaceuticals, Inc. ("Orchid Delaware") and am Vice President of Business Development & Operations of Orgenus Pharma, Inc. ("Orgenus"). I am authorized to make this statement on their behalf. I have personal knowledge of the facts asserted herein and, if called as a witness, could and would competently testify to these matters.

2. Orchid Delaware is a Delaware corporation, and has named as its agent Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808. Orchid Delaware is a wholly-owned subsidiary of Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid India").

3. Orchid Delaware's Board of Directors is composed of Mr. K. Raghavendra Rao, Ms Edna Braganza, and myself.

4. Orchid Delaware is a holding company. It has no offices or employees in Delaware, and had a $0 tax estimate as of January 2008.

5. Orchid Delaware keeps its own books and records and makes its own strategic decisions.

6. Orchid Delaware is, and holds itself out to the public as, a separate corporate entity from its parent, Orchid India. Orchid Delaware maintains corporate formalities.

7. Orchid Delaware is not the designated agent of Orchid India, nor does it represent itself as such. It does not have the power to act or sign for Orchid India, and cannot otherwise bind Orchid India to any contractual obligations.

8. Orchid Delaware did not participate in, contribute to, or otherwise aid in the preparation of ANDA No. 90-044 or in its submission to the FDA.

9. Orgenus is a New Jersey corporation with its principal place of business in Princeton, NJ. It is a wholly-owned subsidiary of Orchid Delaware.

10. Orchid Healthcare, Ltd., a division of Orchid India, named Orgenus its U.S. regulatory agent for purposes of submitting documents regarding generic memantine hydrochloride drug products to the FDA.

[redacted]

13. Orgenus publicly disclosed that it is Orchid Healthcare's regulatory agent in the U.S. in a Suitability Petition filed on behalf of Orchid Healthcare with the FDA on May 18, 2007, regarding a proposed new formulation for generic memantine hydrochloride drug products. *See* Exhibit B.

14. Orgenus is presently involved in unrelated litigation arising from submission of other ANDAs by Orchid Healthcare in the District of New Jersey. Orgenus has not challenged personal jurisdiction in that district.

I declare under penalty of perjury and the laws of the United States that the foregoing is true and correct.

Dated: March 3, 2008 *_____/s/ Satish Srinivasan_____*

Public Version Dated: March 7, 2008 Satish Srinivasan

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FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on March 7, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on March 7, 2008, the attached document was Electronically Mailed to the following person(s):

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EXHIBIT A

THIS EXHIBIT HAS BEEN
REDACTED IN ITS ENTIRETY

EXHIBIT B

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Orgenus

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

SUITABILITY PETITION

Dear Sir or Madam:

Orgenus Pharma, Inc. hereby submits this Suitability Petition on behalf of Orchid Healthcare as its US Agent.

This petition is submitted, in quadruplicate, pursuant to 21 CFR § 10.20 and § 10. 30, as provided for in 21 CFR § 314.93 and section 505(j)(2)(C) of the Federal Food, Drug and cosmetic Act, to request the commissioner of the Food and Drug Administration to declare that the drug product Memantine Hydrochloride Orally Disintegrating Tablets 5 mg and 10 mg are suitable for submission as an abbreviated new drug application (ANDA).

Action Requested

The petitioner requests that the commissioner of the Food and Drug Administration declare that Memantine Hydrochloride Orally Disintegrating Tablets 5 mg and 10 mg are suitable for submission as an ANDA. The reference listed drug products (RLDs) upon which this petition is based are Namenda ® Tablets 10 mg & 5 mg (NDA # 021487) and Oral Solution 2 mg / ml (NDA # 021627), manufactured by Forest Pharmaceuticals Inc. (See copy of the page from the current Electronic Edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, Attachment 1). The petitioner seeks a change in dosage form (from the approved dosage forms of tablets and solution to an orally disintegrating tablets) from that of the RLD products.

Statement of Grounds

The proposed drug product, Memantine Hydrochloride Orally Disintegrating Tablets, is presented for administration by placing on the tongue, which will disintegrate in a matter of seconds and swallowing the disintegrated tablet with or without water.

The Orally Disintegrating Tablets would be a viable alternative to both of the currently marketed dosage forms, Tablets and Oral Solution, due to the following advantages:

- Convenient for patients who have difficulty in swallowing tablet dosage form.
- Unit dose dispensing of drug (in comparison with solution form).
- Does not require a dosing device as in solution form.

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- Ease of carrying (in comparison with a bulky solution container).
- Ease of administration. Administration with water is not required.

The proposed product will differ only in dosage form. The indications, strengths, route of administration, intended patient population and recommendations for use will remain the same as of the RLD products. The proposed product will be formulated so as to be bioequivalent to current tablet formulation (RLD), marketed by Forest Pharmaceuticals Inc. The proposed product will contain inactive ingredients that are generally recognized as safe (GRAS) and at levels previously approved by USFDA. Therefore there will be no difference between the safety and efficacy of the proposed product and RLD products.

The proposed product will be labeled in accordance with the approved labeling of RLD products upon which this petition is based. Any difference in labeling will relate only to the differences in dosage forms. The indications, warnings, dosage, route of administration and intended patient population will remain the same as that of RLD products.

Therefore the petitioner requests the commissioner to find that a change in dosage form from Tablets and Oral Solution to Orally Disintegrating Tablets should raise no questions of safety or effectiveness and the Agency should approve the petition.

Pediatric Use Information

The petitioner is aware that, according to the Pediatric Research Equity Act (PREA) of 2003, which amended the FDC Act, a pediatric assessment is required for a new proposed product with a new dosage form.

The petitioner hereby requests that a waiver from the conduct of pediatric studies under 21 U.S.C. § 355c(a)(4)(A) pursuant to 21 CFR § 314.55(c)(2)(i) be granted for the approval of this petition to permit a subsequent ANDA filing. The request for waiver is justified as the drug or biological product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients and is not likely to be used in substantial number of pediatric patients.

For the aforementioned reasons, the undersigned requests that the Commissioner grant this petition and authorize submission of an ANDA for Memantine Hydrochloride Orally Disintegrating Tablets 5 mg and 10 mg.

Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR § 25. 31.

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Economic Impact

The petitioner does not believe that this is applicable in this case, but will agree to provide such an analysis if requested by the agency.

Certification

The undersigned certifies that to the best of his knowledge, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which is unfavorable to the petition.

Sincerely,

Satish Srinivasan
Director, Business Development & Operations

Attachments:

1. Approved Drug Products with Therapeutic Equivalence Evaluations
2. Draft labeling proposed for Memantine Hydrochloride Orally Disintegrating Tablets
3. Labeling for the RLD, Namenda ® Tablets / Oral Solution

Namenda ® is registered Trademark of Forest Pharmaceuticals Inc.

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